March 24, 2023

Palliare Ltd.
% Paul Dryden
Consultant
Palliare Ltd. c/o ProMedic Consulting, LLC
131 Bay Point Dr. NE
St. Petersburg, Florida 33704

Re: K230474
Trade/Device Name: EVA5 Insufflator
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: FCX
Dated: February 21, 2023
Received: February 22, 2023

Dear Paul Dryden:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's

requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Sivakami Venkatachalam -S

for
Shanil P. Haugen, Ph.D.
Assistant Director
DHT3A: Division of Renal, Gastrointestinal,
Obesity and Transplant Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230474

Device Name

EVA5 Insufflator

Indications for Use *(Describe)*

The EVA5 Insufflator is intended for use in diagnostic and/or therapeutic endoscopic procedures to distend the gastrointestinal tract by filling it with gas.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

Date Prepared:	14-Mar-23
	Palliare Ltd. Galway Business Park, Dangan Galway H91 P2DK, Ireland
Official Contact:	John O'Dea, Ph.D., CEO
Submission Correspondent:	Paul Dryden ProMedic, LLC
Proprietary or Trade Name:	EVA5 Insufflator
Classification Panel:	Gastroenterology/ Urology
Regulatory Class:	Class II
Common/Usual Name: **Regulation Number: Product Code:**	CO_2 insufflator 21 CFR 876.1500 FCX – Insufflator, Automatic Carbon-Dioxide For Endoscope
Primary Predicate Device: **Common/Usual Name:** **Regulation Number: Product Code:**	K193520 – Palliare EVA15 CO_2 insufflator 21 CFR 876.1730 HIF – Insufflator, Automatic Carbon-Dioxide For Endoscope
Secondary Predicate Device: **Common/Usual Name:** **Regulation Number: Product Code:**	K222901 – Palliare EVA15 CO_2 insufflator 21 CFR 876.1730 HIF and FCX – Insufflator, Automatic Carbon-Dioxide For Endoscope

Device Description:
The EVA5 insufflator is intended for use in diagnostic and/or therapeutic endoscopic procedures to distend a cavity by filling it with gas. It is indicated to facilitate the introduction of various endoscopic instruments by filling the alimentary canal with gas to distend it. The EVA5 Insufflator is used in an operating room or endoscopic suite. It consists of the following major component (1) a micro-processor-controlled insufflation flow control system.

The EVA5 Insufflator is an active medical device, nonsterile and reusable and is intended to insufflate the alimentary canal via an endoscope. The EVA5 is powered by AC and uses a compressed 50 psi CO_2 gas supply to supply the pneumatic circuitry for insufflation.

Principle of Operation:
EVA5 employs a proportional flow control solenoid in series with a flow sensor which provides flow feedback. The flow delivery pneumatics are identical to those used in the predicate K193520.

Indications for Use:
The EVA5 Insufflator is intended for use in diagnostic and/or therapeutic endoscopic procedures to distend the gastrointestinal tract by filling it with gas.

Patient Population:
Patient undergoing endoscopic procedures in which insufflation may be helpful.

Environments of use:
Operating room or endoscopy suite.

Table 1 is a comparison – Subject Device vs. the Primary Predicate, K193520 and Secondary Predicate K222901 – Palliare EVA 15.

Substantial Equivalence Discussion
The EVA5 insufflator has a narrowed intended use and indications, and the same technological characteristics, and principles of operation as the predicate Palliare EVA 15, K193520.

Intended Use/ Indications for Use
The EVA5 Insufflator is intended for use in diagnostic and/or therapeutic endoscopic procedures to distend the gastrointestinal tract by filling it with gas. The proposed modifications to the indications for use are essentially a restricted subset of those for the which the predicate Palliare EVA15 Insufflator, K193520, was cleared.

Modification:
The primary predicate K193520 had the following indications and intended uses.

The EVA15 Insufflator is intended for use in diagnostic and/or therapeutic endoscopic and laparoscopic procedures to distend the abdomen, colon or thoracic cavity with up to 15 mmHg pressure, by filling it with gas and to evacuate surgical smoke.

The insufflator offered both fixed flow and pressure endoscopic and laparoscopic insufflation modalities and smoke evacuation (cleared with HIF Procode)

The secondary predicate K222901 had the following indications and intended uses.

The EVA15 Insufflator is intended for use in diagnostic and/or therapeutic endoscopic and laparoscopic procedures to distend the abdomen, rectum, colon, esophagus, stomach or thoracic cavity with up to 25 mmHg pressure, by filling it with gas and to evacuate surgical smoke.

The insufflator offers only pressure insufflation and smoke evacuation (cleared with HIF and FCX Product Codes)

The EVA5 insufflator offers only fixed flow insufflation and no smoke evacuation, thus the appropriate ProCode would be FCX.

Technological Characteristics
The modification does not change the technological characteristics. See Table 1 below on page 4 of 5 and page of 5 of 5.

Principles of Operation
The EVA5 Insufflator principle of operation for flow delivery is identical to the predicates K193520 and K222901.

Non-clinical Testing
Performance testing of the insufflator demonstrated that the subject device met its acceptance criteria, which are similar to the predicate (±0.3 SLPM (EVA5) versus ±1 SLPM (EVA15) specifications).

Testing included:

- Flow accuracy
- Switch-off time accuracy

Substantial Equivalence Conclusion
The EVA5 with the modified indications represents a restricted subset of the intended use and has similar indications, technological characteristics and principles of operation as the predicate K193520.

This difference does not present different questions of safety or effectiveness than the predicate device because K193520 offered a fixed flow mode. EVA5 delivers a subset of the flow range cleared in K193520 Thus, the fixed flow mode of insufflation offered in the EVA5 Insufflator is substantially equivalent to that offered in the Palliare EVA 15, cleared under K193520.

510(k) Summary

Table 1 – Comparison – Subject vs. Predicates

	Proposed Device: EVA5 Insufflator	**Primary Predicate: EVA15 Insufflator - K193520**	**Secondary Predicate: EVA15 Insufflator – K222901**	**Comparison**
Manufacturer	Palliare	Palliare	Palliare	
Classification	21 C.F.R. § 876.1500 (*Endoscopic Insufflator*), Product Code FCX	21 C.F.R. § 884.1730 (*Laparoscopic Insufflator*), Product Code HIF	21 C.F.R. § 884.1730 (*Laparoscopic Insufflator*), Product Code HIF and FCX	The predicate has the insufflator intended use that is under FCX, but the FDA clearance did not include FCX. However, the secondary predicate K222901 includes the FCX Code
Fundamental scientific technology	Digital insufflation flow regulation system using compressed CO_2 gas.	Digital insufflation flow regulation and pressure regulation system using compressed CO_2 gas. Venturi smoke evacuation.	Digital insufflation pressure regulation system using compressed CO_2 gas. Venturi smoke evacuation.	Functionality of K193520 has been split into two devices – a pressure insufflator and a flow insufflator
Patient connection	Endoscope connection	Standard Trocar luer connection or endoscope connection	Standard Trocar luer connection or endoscope connection	K193520 and K222901 can connect to endoscope
Indications for Use	The EVA5 Insufflator is intended for use in diagnostic and/or therapeutic endoscopic procedures to distend the gastrointestinal tract by filling it with gas.	The EVA15 Insufflator is intended for use in diagnostic and/or therapeutic endoscopic and laparoscopic procedures to distend the abdomen, colon or thoracic cavity with up to l5 mmHg pressure, by filling it with gas and to evacuate surgical smoke.	The EVA15 Insufflator is intended for use in diagnostic and/or therapeutic endoscopic and laparoscopic procedures to distend the abdomen, rectum, colon, esophagus, stomach or thoracic cavity with up to 25 mmHg pressure, by filling it with gas and to evacuate surgical smoke.	Proposed device has IFU which are a subset of K193520 IFU but describing the anatomical location more generally

	Proposed Device: EVA5 Insufflator	**Primary Predicate: EVA15 Insufflator - K193520**	**Secondary Predicate: EVA15 Insufflator – K222901**	**Comparison**
Gas Delivery Modes	Fixed Flow	Fixed Flow Intermittent Pressure (Standard) Insufflation Continuous Pressure Insufflation	Intermittent Pressure (Standard) Insufflation Continuous Pressure Insufflation	Proposed device has Fixed Flow which are a subset of K193520 features
Smoke Evacuation	N/A	Available in all modes. Operates continuously or may be activated on/off using foot pedal.	Available in all modes. Operates continuously or may be activated on/off using foot pedal.	Proposed device does not have Smoke Evac (not required in Endoscopic applications)
Flow Range	0-4 SLPM	0-40 SLPM	0-40 SLPM	Proposed device has flow range which is a subset of K193520 and K222901
Pressure Range	N/A	7-15 mmHg	7-25 mmHg	Proposed device does not offer pressure insufflation
Accessories	None	Tubesets	Tubesets	EVA15 works with any commercial water bottle tubeset
Dimensions	160x130x330mm	160x130x330mm	160x130x330mm	Same
Weight	5.0kg	5.5kg	5.5kg	Lighter on account of no smoke evacuation pneumatics
Power Source	100-240V	100-240V	100-240V	Same
User Interface	Membrane Panel	Membrane Panel	Membrane Panel	Same
Automatic Switch-off time	30, 60, 90, 120 minutes	N/A	N/A	A user feature